

**IN THE CLAIMS**

Claims 1-97 (Cancelled)

98. (New) A method for customizing medical protocols, comprising the steps of:

receiving data related to one or more patients;

customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from among a large number of possible data elements, and/or from a pull down menu, and entering the corresponding data elements into the fields of a database, to derive one or more customized medical protocols;

automatically transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

the one or more medical monitoring devices communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information; and

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device.

99. (New) The method of claim 98, further comprising the step of:

said second device analyzing said patient-reported information according to risk posed to the patient's health, and transmitting prompt transmissions to one or more additional devices based upon the risk posed to the patient's health by the patient-reported information, or storing said information for later review.

100. (New) The method of claim 98 wherein the patient-reported information includes information concerning specific medications including side effects, and/or adherence to medication schedules, and/or medication compliance, and/or adverse effects.

101. (New) The method of claim 98 wherein the transmission of prompt transmissions is determined through automatic analysis by the second device.

102. (New) The method of claim 98, wherein the second device can poll the medical monitoring device, said frequency of said polling is determined by an analysis of the patient-reported information.

103. (New) The method of claim 98, wherein the determination of which one or more additional devices are to receive specific prompt transmissions, and which additional devices are not to receive specific prompt transmissions, is determined by automatic analysis of the patient-reported information.

104. (New) The method of claim 103 wherein the timing of such transmission, and the data conveyed to an additional device is determined by the automatic analysis.

105. (New) The method of claim 98, wherein either the medical monitoring device issues a prompt transmission to the patient, or the second device issues a prompt transmission to the medical monitoring device for review by the patient, based upon the execution of an analysis of the patient-reported information.

106. (New) The method of claim 98, wherein the second device exchanges communications with additional information management systems and databases.

107. (New) The method of claim 106 wherein the medical monitoring device and/or the second device can download from the additional information management systems and databases additional information to the patient, and communicate new instructions.

108. (New) The method of Claim 98 wherein the second device analyzes the patient-reported data, and downloads information to the medical monitoring device to initiate treatments.

109. (New) The method of Claim 98 wherein the second device provides on-demand data exchanges with system users.

110. (New) The method of the claim 109 wherein a security manager employs role based assignments to authenticate system users and validate queries.

111. (New) The method of claim 98 wherein the second device includes a database manager and information management system that uses logic rules and similar inference methodologies to query the contents of the information management system which include the patient-reported data.

112. (New) The method of claim 98 wherein the second device includes a database processor that provides business logic rules and similar inference methodologies that support data mining and diagnostic reasoning functions of the patient-reported data.

113. (New) The method of claim 109 wherein the data exchanges include reports to system users.

114. (New) The method of claim 98 wherein the customized medical protocol is created by selecting a combination of data elements from a patient database residing in the second device, said data elements including a personal questionnaire for a specific patient, and public questionnaires for a group of patients.

115. (New) The method of claim 98 wherein the stored patient-reported information is stored as event files which are collected by a patient database in an event log that can be accessed as a report.

116. (New) The method of claim 109 wherein said reports include medication compliance ratios, and/or questionnaire responses.

117. (New) The method of claim 98 wherein a specific medical protocol may be remotely modified for a subgroup of patients who share one or more common characteristic, as well as specific patient instructions for individualized components of the medical protocols.

118. (New) The method of claim 98 wherein the medical treatment protocol includes individual medication using and dosing instructions on a specific medication or combinations of medications, and/or educational content, and/or questionnaires.

119. (New) The method of claim 117 wherein the medical protocol is modified based upon the patient's inclusion in a particular group that shares one or more common characteristics.

120. (New) The method of claim 98 , wherein the second device instantaneously remotely updates the medical protocol in the medical monitoring device.

121. (New) The method of claim 106 wherein other databases are searched for content that is specific to a population, or subpopulation of patients, or to an individual patient.

122. (New) The method of claim 98, wherein the prompt transmission of information is determined by whether the patient-reported information falls outside the range of valid values for the particular data element or data elements contained within the patient-reported information.

123. (New) The method of claim 98 wherein the patient-reported information includes vital signs and other biological measurements that are manually entered and/or entered by physiologic monitoring devices into the medical monitoring device.

124. (New) The method of claim 98 wherein the customized medical protocol may includes medication type, and/or medication dosage, and/or dietary regimen, and/or specific reminders as to when to obtain a medication refill, and and/or when to call the doctor, and/or any algorithm-driven events based upon data inputted by the patient.

125. (New) The method of claim 98 wherein the analysis of risk is performed by biostatistical analysis and stratification of patients based upon their respective risks of developing worsening clinical outcomes.

126. (New) The method of claim 98 wherein a biostatistical analysis results in a risk stratification of patients based upon their risks of developing worsening clinical outcomes, and/or increased medical costs, to broadcast relevant information in real-time to one or more additional devices.

127. (New) The method of claim 108 wherein the downloaded information is based upon medical decision support software that instantaneously updates a patient management protocol.

128. (New) The method of claim 99 wherein the content of the information contained in the transmission of prompt transmissions to additional devices is based upon role-based assignments for the users of each device, wherein their assigned role determines which content they receive.

129. (New) The method of claim 99 wherein the transmission of the information is timed to prompt the user of the additional device to carry out or modify sequential treatment interventions with the patient.

130. (New) The method of claim 129 wherein the timing of transmission and the timing of the interventions is in real-time.

131. (New) The method of claim 99 wherein the one or more additional devices communicates the prompt transmission via a message presented in textual, graphic, pictorial, or voice formats.

132. (New) The method of claim 131 wherein the message is in the form of raw patient data or reports.

133. (New) The method of claim 101 wherein the analysis of said patient-reported information according to the risk posed to the patient's health determines the probability of a decline in the patient's health and/or increased cost of health care.

134. (New) The method of claim 99 wherein the prompt transmission to one or more additional devices is determined by whether the patient-reported information falls outside a range of valid values stored in the second device.

135. (New) The method of claim 99 wherein the one or more additional devices download modified medical treatment protocols to one or more medical monitoring devices based upon the analysis of the patient-reported information.

136. (New) The method of claim 98 wherein one patient interacts with at least two medical devices.

137. (New) The method of claim 134 wherein the range of valid values in the second device is selected from a menu, or determined for the one or more patients based upon population-based or individual patient standards.

138. (New) The method of claim 98 wherein the communication of the customized medical protocol and/or information to the one or more patients is presented via graphic and/or audible communications.

139. (New) The method of claim 138 wherein the audible communications are in the form of voice communications.

140. (New) The method of claim 98 wherein the medical protocols reside in the database, and are directly transferred to one or more medical monitoring devices and are communicated to the patient by the one or more devices.

141. (New) The method of claim 98 wherein one or more medical monitoring devices may be a telephone and/or a personal digital assistant.

142. (New) The method of claim 99 wherein the one or more additional devices may be a telephone and/or a personal digital assistant, and/or a desktop personal computer and/or a laptop computer or other computing device.

143. (New) A method for customizing medical protocols, comprising the steps of: receiving data related to one or more patients;

customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from among a large number of possible data elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;

automatically transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter information related to medication compliance and health status;

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith from a medical database to the one or more medical monitoring devices; and receiving patient information from the one or more medical monitoring devices, including medication compliance information for one or more medications taken by the patient, following the patient interaction with the medical monitoring device;

said second device analyzing said patient information based upon a statistical analysis of the dose-specific effects of the medication on the patient.

144. (New) The method of claim 143 wherein the medical database combines the patient medication compliance and health status information with other database information for statistical analysis and data mining.

145. (New) The method of claim 144 wherein the statistical analysis and data mining are used to determine the relationship between drug doses, and/or patient outcomes, and/or costs of treatment.

146. (New) The method of claim 145 wherein the statistical analysis and data mining are used to predict the responses of subpopulations of patients to one or more medications taken by the patients.

147. (New) The method of claim 146 wherein the subpopulations of patients share specific genetic and physical attributes.

148. (New) The method of claim 143 wherein the statistical analysis and data mining is used to adjust the dosing of the medication, and/or improve clinical outcomes, and/or reduce the frequency of side effects and/or adverse drug events, and/or determine the most cost-effective way of means of using the medications.

149. (New) The method of claim 98 wherein the communication of the customized medical protocol and/or information to the one or more patients includes a musical alarm that is most motivating for the one or more patients to adhere to the medical protocol.

150. (New) The method of claim 98 wherein the communication of the customized medical protocol and/or information to the one or more patients is in the form of pictorial representations and/or streaming video.

151. (New) The method of claim 143 wherein the communication of the customized medical protocol and/or information to the one or more patients is in the form of pictorial representations and/or streaming video.

152. (New) The method of claim 98 wherein the communication of the customized information includes an advertisement.

153. (New) The method of claim 143 wherein the communication of the customized information includes an advertisement.

154. (New) The method of claim 143 wherein the communication of the customized medical protocol and/or information is presented via graphic and/or auditory communications.

155. (New) A method for customizing medical protocols, comprising the steps of: receiving data related to one or more patients;

customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from among a large number of possible data elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;

automatically transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, said information including an advertisement, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information;

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device;

    said second device analyzing said patient-reported information.

156. (New) The method of claim 155 in which the information is in the form of graphic and/or audible communications.

157. (New) The method of claim 155 wherein the content of the advertisement is selected based upon one or more attributes shared by the one or more patients.

158. (New) The method of claim 155 wherein the analysis of the patient-reported information by the second device is used to modify the content of the advertisement.

159. (New) The method of claim 155 wherein the analysis of the patient-reported information by the second device is combined with analysis of data from one or more additional databases, to modify the advertisement.

160. (New) The method of claim 159 wherein the analysis is used to select the correct advertising to increase the sales of one or more medications.

161. (New) The method of claim 158 wherein the modification of the advertisement related to a medication is for the purpose of optimizing the patient's adherence to the medication and/or patient outcomes.

162. (New) The method of claim 159 wherein the modification of the advertisement related to a medication is for the purpose of increasing the frequency of prescribing that medication by physician prescribers.

163. (New) A method for customizing medical protocols, comprising the steps of:

- receiving data related to one or more patients;
- customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from a large number of possible data elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;
- automatically transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;
- using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information;
- using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device;
- combining said patient-reported information with information contained in one or more additional databases
- analyzing said combined information for the purpose of improving health outcomes, and/or medication adherence, and/or the accuracy of drug labeling and medication package insert information, and/or the marketing and sales communications for a medication, and/or reducing the cost of healthcare.

164. (New) The method of claim 98, wherein the one or more medical devices used by the patient communicates with one or more medication containers that are separate from the one or more medical devices.

165. (New) The method of claim 163 wherein the one or more medical monitoring devices communicating the customized medical protocol and/or information to the one or more patients communicates via graphic and/or audible messages.

166. (New) The method of claim 165 wherein the graphic and/or audible messages include one or more advertisements.

167. (New) The method of claim 163 wherein the patients receiving a specific medical protocol and/or information belong to a subpopulation of patients.

168. (New) The method of claim 98 wherein new software code is remotely downloaded from the second device to one or more of the medical monitoring devices, to assist the patient in following a medical protocol.

169. (New) The method of claim 168 wherein the medical monitoring devices used by two or more patients sharing one or more attributes receive the same software code.

170. (New) The method of claim 163 wherein the selection of a medical monitoring device for a specific patient is based upon an analysis of the patient-reported information.

171. (New) A method for customizing medical protocols, comprising the steps of:  
receiving data related to one or more patients;  
customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from a large number of possible data elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;

automatically, transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information;

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device;

the medical monitoring device providing an interactive screen and/or interactive voice prompt to enable the patient to receive medical information from a database residing in one or more additional devices.

172. (New) The method of claim 171 wherein the interactive screen displays symbols and/or key words signifying the type of medical information to be accessed.

173. (New) The method of claim 171 wherein the information residing in the database supports the patient's specific medical protocol to optimize the outcome of the patient's medical treatment.

174. (New) The method of claim 172 wherein a displayed symbol and/or key word may be dynamically altered based upon rules-based software residing in the medical monitoring device and/or the second device.

175. (New) The method of claim 172 wherein the assignment of the symbols and/or key words is related to one or more characteristics of a single patient, or shared by two or more patients who receive identical symbols and/or key words.

176. (New) A method for customizing medical protocols, comprising the steps of:  
receiving data related to one or more patients;  
customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from a large number of possible data

elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;

automatically transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information;

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device;

combining said patient-reported information with additional information contained in a database residing in said second device; and

analyzing said combination of patient-reported information with other information contained in the database for the purpose of predicting the responses of subpopulations of patients to a given drug or combination of drugs, and/or adjust dosing recommendations, and /or determine the most cost-effective means of using drugs to improve the health of specific populations of patients.

177. (New) A method for customizing medical protocols, comprising the steps of:  
receiving data related to one or more patients;

customizing one or more medical protocols based on the received data, by selecting a combination of data elements for a medical treatment plan from a large number of possible data elements, and/or data elements from a pull down menu, and entering the corresponding data elements into one or more fields of a database, to derive one or more customized medical protocols;

automatically, transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients;

using the one or more medical monitoring devices for communicating the customized medical protocol and/or information to the one or more patients, and the one or more patients interacting with said one or more medical monitoring devices to enter patient-reported information;

using a second device for transmitting the one or more customized medical protocols and/or information associated therewith to the one or more medical monitoring devices; and receiving patient-reported information from the one or more medical monitoring devices following the patient interaction with the medical monitoring device;

wherein said second device has residing within it a database providing information about one or more patients, wherein a user may execute a transaction to access said information by making a payment, and wherein said database records said transaction.

178. (New) The method of claim 143 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

179. (New) The method of claim 155 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

180. (New) The method of claim 163 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

181. (New) The method of claim 171 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

182. (New) The method of claim 176 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

183. (New) The method of claim 177 wherein the second device provides on-demand data exchanges with system users wherein the data exchanges include reports to system users.

184. (New) The method of claim 99 wherein said prompt transmission includes a communication of a decision support protocol including recommended interventions.

185. (New) The method of claim 98 wherein the medical monitoring device delivers an audible alarm selected to facilitate the patient's adherence to the medical treatment plan.

186. (New) The method of claim 176 wherein the information may be in the form of a video and/or pictorial representation.

187. (New) The method of claim 98 wherein the database is imported into additional databases.